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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09 238,741	01/28/1999	GARY R. BRASLAWSKY	012712-584	5956

909 5890 06/04/2003

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EXAMINER

HELMS, LARRY RONALD

ART UNIT	PAPER NUMBER
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1642

DATE MAILED 06/04/2003

26

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/238,741

Examiner

Larry R. Helms

Applicant(s)

BRASLAWSKY ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 4-9, 14, 24-29, 34-36, 41 and 45-48 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

- 5) ☐ Claim(s) _____ is/are allowed.

- 6) ☒ Claim(s) 1-2, 4-9, 14, 24-29, 34-36, 41, 45-48 is/are rejected.

- 7) ☐ Claim(s) _____ is/are objected to.

- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1 ☐ Certified copies of the priority documents have been received.
2 ☐ Certified copies of the priority documents have been received in Application No. _____.
3 ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

Attachments

- 1) ☐ Notice of References Cited (PTO-894)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper Notice
4) ☐ Interview Summary (PTO-419) Paper Notice
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other

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DETAILED ACTION

1. Claims 1-2, 4-9, 14, 24-29, 34-36, 41, 45-48 are pending and under examination.
Claims 1, 24, 28, 41 have been amended.
2. The text of those sections of title 35, USC Code not included on the Office Action can be found in a prior Office Action.
3. The following Office Action contains some NEW GROUNDS of rejections.

Oath/Declaration

4. The Examiner acknowledges that a new Declaration will be submitted in due course as indicated in the amendment filed 3/28/03, however, the oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c). The name of the inventor Michael V. LaBarre has been altered to replace the "V" with a "J". In addition the name "Garry R. Braslawsky" has been altered to "Gary Ronald Braslawsky"

Rejections Withdrawn

WITHDRAWN - VIEW OF THE AMENDMENTS OF 3/28/03

6. The rejection of claims 1-2, 4-9, 14, 24-29, 34-36, 41, 47-48 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendments to the claims.

7. The rejection of claims 1-2, 4-9, 14, 24-29, 34-36, 41, 47-48 under 35 U.S.C. 112, first paragraph, is withdrawn in view of the amendments to the claims.

8. The rejection of claims 45-46 under 35 U.S.C. 103(a) as being unpatentable over Caron et al (J. Exp. Med. 176:1191-1195, 1992) and further in view of Fanger et al (Critical Reviews in Immunology 12:101-124, 1992) and Cumber et al (J. Of Immunol. 149:120-126, 1992) and Reff et al [a] (U.S. Patent 6,011,138, filed 2/20/97) and Reff et al [b] (Blood 83:435-445, 1994) is withdrawn in view of the new grounds of rejection

Response to Arguments

9. The rejection of claim 35 under 35 U.S.C. § 112, first paragraph, because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention, because the specification does not provide evidence that the claimed biological materials are (1) known and readily available to the public; (2) reproducible from the written description is maintained.

The response filed 3/28/03 has been carefully considered but is deemed not to be persuasive. The response states that the complete DNA and amino acid sequences for the C2B8 and p5E8 antibodies were in US Patents 5,830,698 and 6,011,138 and the amino acid sequence of RUTUXAN is in US Patent 5,736,137 and it is available from

acid sequence such as the CH1, CH2, CH3, sequences are not and therefore the entire sequence is not disclosed. Although the deposit number of 69119 was given the examiner could not find the cell line in the on line catalog for the ATCC. As such the deposit is still required because it is still not clear if the hybridomas that produce the antibodies are commercially available. The claims require the entire antibodies and the specification teaches combining the molecules but the molecules themselves are required for the practice of the invention.

Response to Arguments/NEW GROUNDS of rejection

10. The rejection of claims 1-2, 4-9, 14, 24-29, 34-36, 41, 45-48 under 35 U.S.C. 103(a) as being unpatentable over Caron et al (J. Exp. Med. 176:1191-1195, 1992, PTO-892) and further in view of Fanger et al (Critical Reviews in Immunology 12:101-124, 1992, PTO-892) and Cumber et al (J. Of Immunol. 149:120-126, 1992, PTO-982) and Reff et al [a] (U.S. Patent 6,011,138, filed 2/20/97, PTO-892) and Reff et al [b] (Blood 83:435-445, 1994, PTO-892) and The Pierce Catalog (pages T-157, T-163-169, 1994-95) is maintained. Claims 45-46 have been added to this rejection because the art of Pierce catalog teaches heterobifunctional crosslinkers to minimize self-conjugation.

The response filed 3/28/03 has been carefully considered but is deemed not to be persuasive. The response states the rejection is improper and relies on an obvious *in vitro* test (see e.g. [a]) and it could not have been anticipated that antibody

multimers exist naturally also does not suggest the outcome of multimers that comprise

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two different antibodies (see page 7 of response). In response to these arguments, Caron et al clearly teaches the advantages of bispecific antibodies and they were superior to conventional IgG (see page 1194). In addition, Fanger teach bispecific antibodies and the antibody binds both antigens. Moreover, Although the antibody of Caron et al is monospecific both antibodies that make up the homodimer bind antigen and it would be reasonable to conclude that a bispecific antibody would also bind both antigens. Because The Pierce Catalog teaches heterobifunctional crosslinkers for conjugation of proteins and the heterobifunctional crosslinkers have the advantage of minimizing undesirable polymerization or self-conjugation which would result in a higher purity of the heterodimeric product and not the undesirable product of a homodimer as is needed in the claims.

Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references. \

Claim Rejections - 35 USC § 112

11. Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 is indefinite for reciting the dimer of claim 2 wherein the dimer is reactive against CD23 antigen and/or the CB20 antigen because if the dimmer is a

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"reactive against" because the exact meaning of the phrase is not clear. Does the dimmer perform a chemical reaction or does the phrase mean specifically binds to the antigens?

Conclusions

12. No Claims are allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (703) 306-5879. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

14. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4242.

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Larry R. Helms Ph.D.

703-306-5879

